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NORTHERN DISTRICT OF CALIFORNIA  
JCS

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA  
SAN FRANCISCO DIVISION

MELONEY WRIGHT and DONNY  
WRIGHT, wife and husband; DANYELE  
BACON, a single woman; DIANA BURK,  
a single woman; TIMA LEIPHART, a  
single woman; NUBIA FLORES, a single  
woman; MOLLY KIRKPATRICK, a single  
woman; REYNALDA ALVARADO, a  
single woman; GAYLE ANDERSON, a  
single woman; VERONIQUE PETERS and  
DONNY PETERS, wife and husband;  
LAKEYA BASKOM, a single woman;  
TIFFANY LILLIE, a single woman; and  
LORRAINE FONTANILLA-WEBBER, on  
behalf of her minor daughter, ASHLEY  
WEBBER,

Plaintiffs,

v.

ORTHO-MCNEIL CORPORATION, a  
foreign corporation; JOHNSON &  
JOHNSON, a foreign corporation;  
JOHNSON & JOHNSON SERVICES,  
INC., a foreign corporation; JOHNSON &  
JOHNSON HEALTH CARE SYSTEMS,  
INC., a foreign corporation; JOHNSON &  
JOHNSON RESEARCH &  
DEVELOPMENT, L.L.C., a foreign  
corporation; JOHNSON & JOHNSON  
CONSUMER COMPANIES INC., a  
foreign corporation; MCKESSON  
CORPORATION, a Delaware corporation;  
ALZA CORPORATION, a California

Case No. **07 2541**  
**DEFENDANTS' ANSWER TO  
PLAINTIFFS' COMPLAINT; DEMAND  
FOR JURY TRIAL**

corporation aka ALZA DEVELOPMENT  
aka ALZA INTERNATIONAL, INC., and  
DOES 1-50,

Defendants.

Defendants Ortho-McNeil Pharmaceutical, Inc. (erroneously sued herein as  
"Ortho-McNeil Corporation") ("OMP"), Johnson & Johnson ("J&J"), Johnson &  
Johnson Services, Inc. ("JJSI"), Johnson & Johnson Health Care Systems, Inc.  
("JJHCS"), Johnson & Johnson Pharmaceutical Research & Development, L.L.C.  
("JJPR&D"), Johnson & Johnson Consumer Companies, Inc. ("JJCC"), Alza Corporation  
(erroneously sued herein as "Alza Corporation aka Alza Development aka Alza  
International, Inc.") ("Alza"), and McKesson Corporation ("McKesson") (collectively,  
"defendants"), by and through counsel, hereby respond to the allegations set forth in  
plaintiffs' Complaint (the "Complaint"), as follows:

### ANSWER TO PARTIES

1. Defendants are without knowledge or information sufficient to form a  
belief regarding the truth of the averments set forth in Paragraph 1.

2. Defendants are without knowledge or information sufficient to form a  
belief regarding the truth of the averments set forth in Paragraph 2.

3. Defendants are without knowledge or information sufficient to form a  
belief regarding the truth of the averments set forth in Paragraph 3.

4. Defendants are without knowledge or information sufficient to form a  
belief regarding the truth of the averments set forth in Paragraph 4.

5. Defendants are without knowledge or information sufficient to form a  
belief regarding the truth of the averments set forth in Paragraph 5.

6. Defendants are without knowledge or information sufficient to form a  
belief regarding the truth of the averments set forth in Paragraph 6.

7. Defendants are without knowledge or information sufficient to form a  
belief regarding the truth of the averments set forth in Paragraph 7.

8. Defendants are without knowledge or information sufficient to form a

1 belief regarding the truth of the averments set forth in Paragraph 8.

2 9. Defendants are without knowledge or information sufficient to form a  
3 belief regarding the truth of the averments set forth in Paragraph 9.

4 10. Defendants are without knowledge or information sufficient to form a  
5 belief regarding the truth of the averments set forth in Paragraph 10.

6 11. Defendants are without knowledge or information sufficient to form a  
7 belief regarding the truth of the averments set forth in Paragraph 11.

8 12. Defendants are without knowledge or information sufficient to form a  
9 belief regarding the truth of the averments set forth in Paragraph 12.

10 13. Defendants admit that J&J is a New Jersey corporations with its principal  
11 places of business in New Jersey. Further answering, defendants deny each and every  
12 remaining allegation and averment set forth in Paragraph 13.

13 14. Defendants admit that J&J, JJSI, JJHCS, and JJCC are New Jersey  
14 corporations with their principal places of business in New Jersey. Defendants further  
15 admit that JJPR&D is a New Jersey limited liability company with its principal place of  
16 business in New Jersey. Further answering, defendants deny each and every remaining  
17 allegation and averment set forth in Paragraph 14.

18 15. Defendants admit that McKesson is a Delaware corporation with its  
19 principal place of business in San Francisco, California and that McKesson conducts  
20 business in California. Further answering, defendants deny each and every remaining  
21 allegation and averment set forth in Paragraph 15.

22 16. Defendants admit that Alza is a Delaware corporation with its principal  
23 place of business in Mountain View, California, and that it is a subsidiary of J&J.  
24 Further answering, defendants deny each and every remaining allegation and averment  
25 set forth in Paragraph 16.

26 17. Defendants admit that OMP is a Delaware corporation with its principal  
27 place of business in New Jersey, that it is a subsidiary of J&J and that OMP conducts  
28 business in California. Further answering, defendants deny each and every remaining

1 allegation and averment set forth in Paragraph 17.

2 18. Defendants deny for want of knowledge, information, and otherwise each  
3 and every allegation and averment set forth in Paragraph 18.

4 19. Defendants deny for want of knowledge, information, and otherwise each  
5 and every allegation and averment set forth in Paragraph 19.

6 20. Defendants admit that OMP and/or JJPR&D designed, manufactured,  
7 marketed, sold and distributed the prescription drug Ortho Evra®. Defendants further  
8 admit that McKesson is a non-exclusive distributor of Ortho Evra®. Defendants further  
9 admit that Ortho Evra® is a transdermal birth control patch. Further answering,  
10 defendants deny each and every remaining allegation and averment set forth in  
11 Paragraph 20.

12 21. Defendants admit that Ortho Evra® was sold and distributed nationwide,  
13 including in California, Arizona, Mississippi and Iowa. Further answering, defendants  
14 deny each and every remaining allegation and averment set forth in Paragraph 21.

15 22. Defendants deny for want of knowledge, information, and otherwise each  
16 and every allegation and averment set forth in Paragraph 22.

17 23. Defendants deny for want of knowledge, information, and otherwise each  
18 and every allegation and averment set forth in Paragraph 23.

19 24. Defendants deny for want of knowledge, information, and otherwise each  
20 and every allegation and averment set forth in Paragraph 24 and further deny the  
21 allegations to the extent they seek to impute wrongdoing and/or liability to defendants or  
22 any of them.

23 25. Defendants admit that OMP and/or JJPR&D distributed the prescription  
24 drug Ortho Evra®. Further answering, defendants deny each and every remaining  
25 allegation and averment set forth in Paragraph 25.

26 26. Defendants deny each and every allegation and averment set forth in  
27 Paragraph 26.

28 27. Defendants admit that OMP and/or JJPR&D distributed the prescription

1 drug Ortho Evra® through licensed physicians in accordance with FDA approved  
2 prescribing information and subject to the precautions, warnings, contraindications and  
3 other information provided with the subject product. Defendants deny for want of  
4 knowledge, information, and otherwise each and every other allegation and averment set  
5 forth in Paragraph 27.

6 **ANSWER TO SUMMARY OF THE CASE**

7 28. Defendants admit that OMP and/or JJPR&D designed, manufactured,  
8 marketed, advertised, sold and distributed the prescription drug Ortho Evra®, which is a  
9 transdermal patch used for the prevention of pregnancy. Further answering, defendants  
10 deny each and every remaining allegation and averment set forth in Paragraph 28.

11 29. Defendants deny each and every allegation and averment set forth in  
12 Paragraph 29.

13 30. Defendants deny each and every allegation and averment set forth in  
14 Paragraph 30.

15 31. Defendants deny each and every allegation and averment set forth in  
16 Paragraph 31.

17 32. Defendants deny each and every allegation and averment set forth in  
18 Paragraph 32 and controvert the prayer for relief contained in Paragraph 32.

19 **ANSWER TO FACTUAL BACKGROUND**

20 33. Defendants admit that OMP and/or JJPR&D designed, manufactured,  
21 marketed, advertised, sold and distributed the prescription drug Ortho Evra®, which is  
22 used for the prevention of pregnancy. Further answering, defendants deny each and  
23 every remaining allegation and averment set forth in Paragraph 33.

24 34. Defendants admit that on or about November 20, 2001, Ortho Evra®  
25 received approval from the FDA as a prescription drug for use by physicians for the  
26 prevention of pregnancy. Further answering, defendants deny each and every remaining  
27 allegation and averment set forth in Paragraph 34.

28 35. Defendants deny for want of knowledge, information, and otherwise each

1 and every allegation and averment set forth in Paragraph 35 and further deny the  
 2 allegations to the extent they seek to impute wrongdoing and/or liability to defendants or  
 3 any of them.

4 36. Defendants deny each and every allegation and averment set forth in  
 5 Paragraph 36.

6 37. Defendants deny each and every allegation and averment set forth in  
 7 Paragraph 37.

8 38. Defendants deny each and every allegation and averment set forth in  
 9 Paragraph 38.

10 39. Defendants deny each and every allegation and averment set forth in  
 11 Paragraph 39.

12 40. Defendants admit that on the Ortho Evra® Website, it states that Ortho  
 13 Evra® works in several ways to help prevent pregnancy including:

- 14 “● It helps prevent ovulation, which means that an egg  
 15 is not released by one of your ovaries for  
 16 fertilization.
- 17 ● It thickens cervical mucus so that sperm are less  
 18 likely to enter your uterus.
- 19 ● It causes changes in the endometrium to reduce the  
 20 likelihood of implantation.”

21 Further answering, defendants deny each and every remaining allegation and averment  
 22 set forth in Paragraph 40.

23 41. Defendants admit that on the ORTHO EVRA® Website, it states that:  
 24 “The transdermal — or ‘through the skin’ — weekly birth control patch prevents  
 25 pregnancy by delivering continuous levels of the hormones norelgestromin and ethinyl  
 26 estradiol (progestin and estrogen, respectively) through the skin and into the  
 27 bloodstream.” Further answering, defendants deny each and every remaining allegation  
 28 and averment set forth in Paragraph 41.



1           42. To the extent Paragraph 42 describes language in the Ortho Evra® label,  
2 defendants state that the label speaks for itself and further answering, defendants deny  
3 each and every remaining allegation and averment set forth in Paragraph 42.

4           43. To the extent Paragraph 43 describes language in the Ortho Evra® label,  
5 defendants state that the label speaks for itself and further answering, defendants deny  
6 each and every remaining allegation and averment set forth in Paragraph 43.

7           44. To the extent Paragraph 44 describes language in the Ortho Evra® label,  
8 defendants state that the label speaks for itself and further answering, defendants deny  
9 each and every remaining allegation and averment set forth in Paragraph 44.

10          45. Defendants deny each and every allegation and averment set forth in  
11 Paragraph 45.

12          46. Defendants deny each and every allegation and averment set forth in  
13 Paragraph 46.

14          47. Defendants deny each and every allegation and averment set forth in  
15 Paragraph 47.

16          48. Defendants deny each and every allegation and averment set forth in  
17 Paragraph 48.

18          49. Defendants deny each and every allegation and averment set forth in  
19 Paragraph 49.

20          50. Defendants deny each and every allegation and averment set forth in  
21 Paragraph 50.

22          51. Defendants are without knowledge or information sufficient to form a  
23 belief regarding the truth of the averments set forth in Paragraph 51.

24          52. Defendants deny each and every allegation and averment set forth in  
25 Paragraph 52.

26          53. Defendants deny for want of knowledge, information, and otherwise each  
27 and every allegation and averment set forth in Paragraph 53.

28          54. Defendants deny for want of knowledge, information, and otherwise each

1 and every allegation and averment set forth in Paragraph 54 and further deny the  
2 allegations to the extent they seek to impute wrongdoing and/or liability to defendants or  
3 any of them.

4 55. Defendants deny each and every allegation and averment set forth in  
5 Paragraph 55.

6 56. Defendants deny each and every allegation and averment set forth in  
7 Paragraph 56.

8 57. Defendants deny each and every allegation and averment set forth in  
9 Paragraph 57.

10 58. Defendants deny for want of knowledge, information, and otherwise each  
11 and every allegation and averment set forth in Paragraph 58 and further deny the  
12 allegations to the extent they seek to impute wrongdoing and/or liability to defendants or  
13 any of them.

14 **ANSWER TO FIRST CAUSE OF ACTION**

15 59. Defendants incorporate by reference, as if fully set forth herein, the answers  
16 to Paragraphs 1 through 58 of the Complaint.

17 60. Defendants state that they were subject only to those duties imposed by  
18 applicable law, and deny the allegations contained in Paragraph 60 to the extent they  
19 suggest any different or greater duties. Defendants further deny that they failed to abide  
20 by any applicable legal duties and further answering, defendants deny each and every  
21 remaining allegation and averment set forth in Paragraph 60.

22 61. Defendants deny each and every allegation and averment set forth in  
23 Paragraph 61.

24 62. Defendants deny each and every allegation and averment set forth in  
25 Paragraph 62.

26 63. Defendants deny each and every allegation and averment set forth in  
27 Paragraph 63 and controvert the prayer for relief contained in Paragraph 63 and the  
28 unnumbered paragraph following Paragraph 63.



**ANSWER TO SECOND CAUSE OF ACTION**

64. Defendants incorporate by reference, as if fully set forth herein, the answers to Paragraphs 1 through 63 of the Complaint.

65. Defendants deny each and every allegation and averment set forth in Paragraph 65.

66. Defendants admit that OMP and/or JJPR&D designed, manufactured, distributed, marketed, promoted and supplied the prescription drug Ortho Evra®, which was expected to reach consumers without substantial change in the condition in which it was sold and further answering, deny for want of knowledge, information, and otherwise each and every allegation and averment set forth in Paragraph 66.

67. Defendants deny for want of knowledge, information, and otherwise each and every allegation and averment set forth in Paragraph 67.

68. Defendants deny each and every allegation and averment set forth in Paragraph 68.

69. Defendants deny each and every allegation and averment set forth in Paragraph 69. Defendants further specifically assert that plaintiffs' strict liability claim for defective design, if any, is barred by reason of the decision of the California Supreme Court in Brown v. Superior Court, 44 Cal. 3d 1049 (1988) and its progeny.

70. Defendants deny each and every allegation and averment set forth in Paragraph 70. Defendants further specifically assert that plaintiffs' strict liability claim for defective design, if any, is barred by reason of the decision of the California Supreme Court in Brown v. Superior Court, 44 Cal. 3d 1049 (1988) and its progeny.

71. Defendants deny each and every allegation and averment set forth in Paragraph 71.

72. Defendants deny each and every allegation and averment set forth in Paragraph 72.

73. Defendants deny each and every allegation and averment set forth in Paragraph 73.

1           74. Defendants deny each and every allegation and averment set forth in  
2 Paragraph 74.

3           75. Defendants deny each and every allegation and averment set forth in  
4 Paragraph 75 and controvert the prayer for relief contained in Paragraph 75 and the  
5 unnumbered paragraph following Paragraph 75.

6                           **ANSWER TO THIRD CAUSE OF ACTION**

7           76. Defendants incorporate by reference, as if fully set forth herein, the answers  
8 to Paragraphs 1 through 75 of the Complaint.

9           77. Defendants deny for want of knowledge, information, and otherwise each  
10 and every allegation and averment set forth in Paragraph 77.

11           78. Defendants deny each and every allegation and averment set forth in  
12 Paragraph 78.

13           79. Defendants deny each and every allegation and averment set forth in  
14 Paragraph 79.

15           80. Defendants deny each and every allegation and averment set forth in  
16 Paragraph 80.

17           81. Defendants deny each and every allegation and averment set forth in  
18 Paragraph 81.

19           82. Defendants deny each and every allegation and averment set forth in  
20 Paragraph 82 and controvert the prayer for relief contained in Paragraph 82 and the  
21 unnumbered paragraph following Paragraph 82.

22                           **ANSWER TO FOURTH CAUSE OF ACTION**

23           83. Defendants incorporate by reference, as if fully set forth herein, the answers  
24 to Paragraphs 1 through 82 of the Complaint.

25           84. Defendants admit that OMP and/or JJPR&D manufactured, promoted,  
26 advertised, sold and distributed the prescription drug Ortho Evra®. Further answering,  
27 defendants deny each and every remaining allegation and averment set forth in Paragraph  
28 84.

1           85. Defendants deny for want of knowledge, information, and otherwise each  
2 and every allegation and averment set forth in Paragraph 85 and deny the allegations to  
3 the extent such allegations seek to impute liability to defendants or any of them.

4           86. Defendants deny for want of knowledge, information, and otherwise each  
5 and every allegation and averment set forth in Paragraph 86 and deny the allegations to  
6 the extent such allegations seek to impute liability to defendants or any of them.

7           87. Defendants deny for want of knowledge, information, and otherwise each  
8 and every allegation and averment set forth in Paragraph 87 and deny the allegations to  
9 the extent such allegations seek to impute liability to defendants or any of them.

10           88. Defendants deny each and every allegation and averment set forth in  
11 Paragraph 88.

12           89. Defendants deny for want of knowledge, information, and otherwise each  
13 and every allegation and averment set forth in Paragraph 89 and deny the allegations to  
14 the extent such allegations seek to impute liability to defendants or any of them.

15           90. Defendants deny for want of knowledge, information, and otherwise each  
16 and every allegation and averment set forth in Paragraph 90.

17           91. Defendants deny each and every allegation and averment set forth in  
18 Paragraph 91.

19           92. Defendants deny each and every allegation and averment set forth in  
20 Paragraph 92 and controvert the prayer for relief contained in Paragraph 92 and the  
21 unnumbered paragraph following Paragraph 92.

22                   **ANSWER TO FIFTH CAUSE OF ACTION**

23           93. Defendants incorporate by reference, as if fully set forth herein, the answers  
24 to Paragraphs 1 through 92 of the Complaint.

25           94. Defendants deny each and every allegation and averment set forth in  
26 Paragraph 94.

27           95. Defendants deny each and every allegation and averment set forth in  
28 Paragraph 95.

1           96. Defendants deny each and every allegation and averment set forth in  
2 Paragraph 96.

3           97. Defendants deny each and every allegation and averment set forth in  
4 Paragraph 97.

5           98. Defendants deny each and every allegation and averment set forth in  
6 Paragraph 98.

7           99. Defendants deny each and every allegation and averment set forth in  
8 Paragraph 99.

9           100. Defendants deny each and every allegation and averment set forth in  
10 Paragraph 100.

11           101. Defendants deny each and every allegation and averment set forth in  
12 Paragraph 101 and controvert the prayer for relief contained in Paragraph 101 and the  
13 unnumbered paragraph following Paragraph 101.

14                           **ANSWER TO SIXTH CAUSE OF ACTION**

15           102. Defendants incorporate by reference, as if fully set forth herein, the answers  
16 to Paragraphs 1 through 101 of the Complaint.

17           103. Defendants deny each and every allegation and averment set forth in  
18 Paragraph 103.

19           104. Defendants deny each and every allegation and averment set forth in  
20 Paragraph 104.

21           105. Defendants deny each and every allegation and averment set forth in  
22 Paragraph 105.

23           106. Defendants deny each and every allegation and averment set forth in  
24 Paragraph 106.

25           107. Defendants deny each and every allegation and averment set forth in  
26 Paragraph 107.

27           108. Defendants deny each and every allegation and averment set forth in  
28 Paragraph 108.

1 109. Defendants deny each and every allegation and averment set forth in  
2 Paragraph 109 and controvert the prayer for relief contained in Paragraph 109 and the  
3 unnumbered paragraph following Paragraph 109.

4 **ANSWER TO SEVENTH CAUSE OF ACTION**

5 110. Defendants incorporate by reference, as if fully set forth herein, the answers  
6 to Paragraphs 1 through 109 of the Complaint.

7 111. Defendants deny each and every allegation and averment set forth in  
8 Paragraph 111.

9 112. Defendants deny each and every allegation and averment set forth in  
10 Paragraph 112.

11 113. Defendants deny each and every allegation and averment set forth in  
12 Paragraph 113.

13 114. Defendants deny each and every allegation and averment set forth in  
14 Paragraph 114 and controvert the prayer for relief contained in Paragraph 114 and the  
15 unnumbered paragraph following Paragraph 114.

16 **ANSWER TO EIGHTH CAUSE OF ACTION**

17 115. Defendants incorporate by reference, as if fully set forth herein, the answers  
18 to Paragraphs 1 through 114 of the Complaint.

19 116. Defendants deny each and every allegation and averment set forth in  
20 Paragraph 116.

21 117. Defendants state that the text of the California Business & Professions  
22 Code speaks for itself and further answering, defendants deny the allegations and  
23 averments set forth in Paragraph 117.

24 118. Defendants deny each and every allegation and averment set forth in  
25 Paragraph 118.

26 119. Defendants deny each and every allegation and averment set forth in  
27 Paragraph 119.

28 120. Defendants deny each and every allegation and averment set forth in

1 Paragraph 120.

2 121. Defendants deny each and every allegation and averment set forth in  
3 Paragraph 121.

4 122. Defendants deny each and every allegation and averment set forth in  
5 Paragraph 122.

6 123. Defendants deny each and every allegation and averment set forth in  
7 Paragraph 123 and controvert the prayer for relief contained in Paragraph 123.

8 124. Defendants deny each and every allegation and averment set forth in  
9 Paragraph 124 and controvert the prayer for relief contained in Paragraph 124 and the  
10 unnumbered paragraph following Paragraph 124.

11 **ANSWER TO NINTH CAUSE OF ACTION**

12 125. Defendants incorporate by reference, as if fully set forth herein, the answers  
13 to Paragraphs 1 through 124 of the Complaint.

14 126. Defendants deny each and every allegation and averment set forth in  
15 Paragraph 126.

16 127. Defendants deny that plaintiffs are entitled to recover any damages,  
17 including but not limited to restitution and punitive damages, and deny the allegations of  
18 Paragraph 127 to the extent such allegations seek to impute liability to defendants or any  
19 of them.

20 128. Defendants state that the text of the California Business & Professions  
21 Code speaks for itself and further answering, defendants deny the allegations and  
22 averments set forth in Paragraph 128.

23 129. Defendants deny each and every allegation and averment set forth in  
24 Paragraph 129.

25 130. Defendants deny each and every allegation and averment set forth in  
26 Paragraph 130.

27 131. Defendants deny each and every allegation and averment set forth in  
28 Paragraph 131.



1 132. Defendants deny each and every allegation and averment set forth in  
2 Paragraph 132 and controvert the prayer for relief contained in Paragraph 132 and the  
3 unnumbered paragraph following Paragraph 132.

4 **ANSWER TO TENTH CAUSE OF ACTION**

5 133. Defendants incorporate by reference, as if fully set forth herein, the answers  
6 to Paragraphs 1 through 132 of the Complaint.

7 134. Defendants are without knowledge or information sufficient to form a  
8 belief regarding the truth of the averments set forth in Paragraph 134.

9 135. Defendants deny each and every allegation and averment set forth in  
10 Paragraph 135 and controvert the prayer for relief contained the unnumbered paragraph  
11 following Paragraph 135 and the unnumbered paragraph following Paragraph 135.

12 **ANSWER TO ELEVENTH CAUSE OF ACTION**

13 136. Defendants incorporate by reference, as if fully set forth herein, the answers  
14 to Paragraphs 1 through 135 of the Complaint.

15 137. Defendants deny each and every allegation and averment set forth in  
16 Paragraph 137.

17 138. Defendants deny each and every allegation and averment set forth in  
18 Paragraph 138 and controvert the prayer for relief contained the unnumbered paragraph  
19 following Paragraph 138 and the unnumbered paragraph following Paragraph 138.

20 **FIRST AFFIRMATIVE DEFENSE**

21 The Complaint fails to state a claim against defendants upon which relief may be  
22 granted.

23 **SECOND AFFIRMATIVE DEFENSE**

24 Plaintiffs' claims are barred by the applicable statute of limitations, statute of  
25 repose, and/or by the equitable doctrines of laches and estoppel.

26 **THIRD AFFIRMATIVE DEFENSE**

27 Plaintiffs' claims are barred by the doctrines of informed consent, release, and  
28

1 waiver.

2 **FOURTH AFFIRMATIVE DEFENSE**

3 Plaintiffs' claims are barred because the alleged damages, if any are proven, were  
4 not proximately caused by any act or omission of any of defendants.

5 **FIFTH AFFIRMATIVE DEFENSE**

6 If plaintiffs suffered any of the injuries, losses, and damages alleged, then said  
7 injuries, losses, and damages were a direct and proximate result of a responsible,  
8 superseding, and/or intervening cause.

9 **SIXTH AFFIRMATIVE DEFENSE**

10 Defendants state that if plaintiffs suffered any of the injuries, losses, and damages  
11 alleged, then said injuries, losses, and damages were due to an allergic, idiosyncratic, or  
12 idiopathic reaction to the product at issue in this case, or by an unforeseeable illness,  
13 unavoidable accident, or preexisting condition, without any negligence and culpable  
14 conduct by defendants.

15 **SEVENTH AFFIRMATIVE DEFENSE**

16 Plaintiffs' injuries and damages, if any, were caused in whole or in part by the acts  
17 (wrongful or otherwise), negligence, sole fault, misuse, abuse, modification, alteration,  
18 omission, or fault of one or more persons or entities over whom defendants exercised no  
19 control and for whom defendants are not legally responsible, including, without  
20 limitation, plaintiffs.

21 **EIGHTH AFFIRMATIVE DEFENSE**

22 Plaintiffs failed to exercise reasonable care and diligence to mitigate their injuries  
23 and damages, if any.

24 **NINTH AFFIRMATIVE DEFENSE**

25 Plaintiffs' claims are barred by the "state of the art" and "state of scientific  
26 knowledge" defenses.

1                                   **TENTH AFFIRMATIVE DEFENSE**

2           Plaintiffs' claims are barred by the Learned Intermediary Doctrine.

3                                   **ELEVENTH AFFIRMATIVE DEFENSE**

4           The product at issue in this case falls under the auspices of the Food, Drug and  
5   Cosmetic Act and regulations promulgated by the Federal Food & Drug Administration,  
6   and therefore Federal law preempts plaintiffs' claims. See 21 U.S.C. §301 et. seq.; see  
7   also 71 Fed. Reg. 3922 (January 24, 2006).

8                                   **TWELFTH AFFIRMATIVE DEFENSE**

9           Defendants did not make to plaintiffs nor did they breach any express or implied  
10   warranties and/or breach any warranties created by law. To the extent that plaintiffs rely  
11   on any theory of breach of warranty, such claims are barred by applicable law, and for  
12   lack of privity with defendants and/or for failure of plaintiffs, or plaintiffs'  
13   representatives, to give timely notice to defendants of any alleged breach of warranty.  
14   Plaintiffs did not rely on any alleged warranty. Defendants further specifically plead as  
15   to any breach of warranty claim all affirmative defenses under the Uniform Commercial  
16   Code existing and which may arise in the future, as enacted in the State of California, and  
17   any other state whose law is deemed to apply in this case.

18                                   **THIRTEENTH AFFIRMATIVE DEFENSE**

19           Plaintiffs' claims are barred by comments j and k to Section 402A of the  
20   Restatement (Second) of Torts.

21                                   **FOURTEENTH AFFIRMATIVE DEFENSE**

22           Plaintiffs' claims of product defects are barred by Section 2, 4, and 6(c) and (d) of  
23   the Restatement (Third) of Torts: Products Liability.

24                                   **FIFTEENTH AFFIRMATIVE DEFENSE**

25           Plaintiffs' product liability claims are barred because the benefits of the relevant  
26   product outweighed its risks.  
27  
28

**SIXTEENTH AFFIRMATIVE DEFENSE**

Plaintiffs' claims are barred in whole or part because the product at issue was at all times properly prepared, packaged, and distributed, and was not defective or unreasonably dangerous.

**SEVENTEENTH AFFIRMATIVE DEFENSE**

Any imposition of punitive damages in this case against defendants is barred to the extent that the manner in which such punitive damages are calculated violates the Constitution of the United States or the Constitution of the State of California.

**EIGHTEENTH AFFIRMATIVE DEFENSE**

Any award of punitive damages in this case against defendants is barred to the extent that the amount of such an award violates the Constitution of the United States or the Constitution of the State of California.

**NINETEENTH AFFIRMATIVE DEFENSE**

Plaintiffs failed to plead a cause of action sufficient to support a claim for punitive damages.

**TWENTIETH AFFIRMATIVE DEFENSE**

Plaintiffs failed to plead fraud with specificity.

**TWENTY-FIRST AFFIRMATIVE DEFENSE**

Plaintiffs' strict liability claim for defective design, if any, is barred by reason of the decision of the California Supreme Court in Brown v. Superior Court, 44 Cal. 3d 1049 (1988) and its progeny.

**TWENTY-SECOND AFFIRMATIVE DEFENSE**

The court lacks personal jurisdiction over one or more defendants.

**TWENTY-THIRD AFFIRMATIVE DEFENSE**

The Complaint fails to state a cause of action against defendants because there is no private right of action under the applicable federal law. To the extent plaintiffs' claims are based on alleged misrepresentations or omissions made to FDA, such claims are barred pursuant to Buckman v. Plaintiffs' Legal Community, 531 U.S. 341 (2001).

**TWENTY-FOURTH AFFIRMATIVE DEFENSE**

Plaintiffs knowingly and voluntarily assumed any and all risks associated with the use of the product at issue, barring in whole or in part the damages plaintiffs seek to recover.

**TWENTY-FIFTH AFFIRMATIVE DEFENSE**

In the event defendants, or any of them, are held liable to plaintiffs, or either of them, which liability is expressly denied, or a settlement of judgment against defendants, or any of them, is reached, Defendants request an apportionment of fault be made as permitted by Li v. Yellow Cab Company, 13 Cal.3d 804 (1975) and American Motorcycle Association v. Superior Court, 20 Cal.3d 578 (1987) and a judgment and declaration of indemnification and contribution be entered against all other persons and entities in accordance with that apportionment of fault.

**TWENTY-SIXTH AFFIRMATIVE DEFENSE**

The amount of any award on behalf of plaintiffs, or either of them, for non-economic loss must be allocated according to the provisions of California Civil Code Section 1431.2 ("Proposition 51").

**TWENTY- SEVENTH AFFIRMATIVE DEFENSE**

Plaintiffs lack standing pursuant to Business & Professions Code Section 17204.

**TWENTY-EIGHTH AFFIRMATIVE DEFENSE**

Defendants specifically reserve the right to amend their Answer by adding defenses, counterclaims, cross claims or by instituting third party actions as additional

1 facts are obtained.

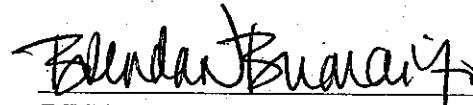
2 WHEREFORE, having fully answered, defendants specifically controvert  
3 plaintiffs' Prayer for Relief including Paragraphs (a) through (h).

4 **JURY DEMAND**

5 Defendants hereby demand a trial by jury of all the facts and issues in this case  
6 pursuant to Federal Rule of Civil Procedure 38(b).

7 Dated: May 14, 2007

8 DRINKER BIDDLE & REATH LLP

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10 BRENDAN N. BUONAIUTO  
11 Attorneys for Defendants  
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